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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,179	03/11/2002	Jeffrey Errington	HO-P02222US0	2178

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,179	ERRINGTON, JEFFREY	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	<i>WLF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the papers filed 7/27/2006 in which claim 26 was amended. Claims 19-30 are pending and under examination in the instant Office action.

Priority

Examiner has obtained a copy of the foreign priority document and it has been placed of record in the file. Benefit of priority has been granted to the filing date of the foreign patent document: 12/22/1998.

Specification

Receipt is acknowledged of a new abstract present on a separate sheet. The objection to the specification is WITHDRAWN in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The rejection of claims 19-20, 26 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is WITHDRAWN in view of Applicant's arguments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods comprising the use of a candidate regulatory sequence from a bacterial essential protein operably linked to a reporter gene, does not reasonably provide enablement for any candidate regulatory sequence operably linked to a reporter gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This rejection is maintained for reasons of record and extended to amended claim 26.**

Response to Arguments

Applicant argues that the application contains "a written description of the invention as currently claimed in such full, clear, concise and exact terms as to enable any person skilled in the art to use the invention" (see page 10, first paragraph of the Remarks filed 7/27/2006). Applicant further argues that the application does enable a person skilled in the art to carry out the methods of the invention using a candidate regulatory sequence that is not a regulatory sequence of the bacterial essential protein. Applicant further argues that the specification at page 18, lines 22-24 teaches that "for any given target gene (*i.e.* any given nucleic acid sequence encoding an essential protein), there is a good probability that somewhere in the genome there will be a regulatory sequence whose activity is enhanced or reduced by lack of the target (*i.e.* essential protein) function" (*ibid*; emphasis added). Applicant further addressed each of the Wands factors in turn, arguing that 1) a person skilled in the art would know "if a particular substance stimulated or inhibited a particular candidate regulatory sequence" (paragraph bridging pages 10-11 of the Remarks filed 7/27/2006); 2) a person skilled in the art can carry out routine control experiments to determine whether or not a particular substance stimulated or inhibited a

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particular candidate regulatory sequence (ibid); 3) Examiner has not provided evidence that confirms that a person skilled in the art could NOT carry out the particular "embodiments" cited within the "Breadth of the Claims" section of the rejection, nor has Examiner provided evidence that such embodiments would not work; 4) it is not necessary to teach all potential embodiments of an invention; 5) Examiner's citation of Allsop et al (*Curr. Opin. Biotech.* 9:637-642, 1998) is irrelevant to the invention; and 6) one of ordinary skill in the art could use the disclosure in combination with his or her common general knowledge to carry out the methods as presently claimed using routine techniques that would not constitute an undue or burdensome amount of experimentation.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. As already set forth in the enablement rejection in the Office action of 1/27/2006, Applicant has only provided one working example of a method for identifying a regulatory sequence which is affected by a feedback mechanism on alteration of synthesis or activity of a bacterial essential protein; the regulatory sequence identified is for the essential protein itself. Further guidance from the specification in the form of a predictive statement that for any given target gene, there is a "good chance" that "somewhere in

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the genome" there will be a regulatory sequence the activity of which is enhanced or reduced by lack of the target function, does not constitute a teaching for how to identify which sequences a) will be affected such that their activity is either enhanced or reduced as a result of a feedback mechanism; and b) which of those sequences are not false positives. In fact, the specification concedes that it may not be possible to predict which genes will be involved in a feedback mechanism other than a promoter of the target, i.e. essential, gene (paragraph bridging pages 4-5). In such cases, the invention provides methods of identifying potential genes which are subject to a feedback mechanism and which are affected by alterations in the activity or synthesis of the essential functional protein under investigation (ibid; emphasis added). Only once such a gene has been identified can a reporter gene under the control of the promoter or regulatory sequences for that gene be readily constructed and incorporated into a bacterial cell for use in accordance with an assay of the invention (ibid). Thus, one of ordinary skill in the art would be required to determine which of these *potential* genes were actually truly affected by the change in essential gene activity/function/amount, before regulatory sequences affected by a feedback mechanism were definitively identified.

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Applicant's arguments directed to the amount of experimentation required for the practice of the invention are not persuasive because it is not enough to state that a person skilled in the art would know if a particular substance stimulated or inhibited a particular candidate regulatory sequence or that a person skilled in the art can carry out routine control experiments to determine whether or not a particular substance stimulated or inhibited a particular candidate regulatory sequence. The identification of regulatory sequences which are affected by a feedback mechanism on alteration or synthesis of a bacterial essential protein is at question, and Applicant has only taught how to identify potential sequences which fulfill the claim limitations, thus burdening one of ordinary skill in the art with the task of determining which of the potential sequences that have been identified as candidates are actually affected by a feedback mechanism on alteration of synthesis or activity of a bacterial essential protein. Given the breadth of the claims, the complex nature of the invention and the lack of guidance provided by the specification and the prior art, such experimentation goes beyond "routine" or simple "control" experiments.

Applicant's argument that Examiner has not cited evidence that the "embodiments" recited in the "Breadth of the Claims"

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section of the rejection under 112, first paragraph, do NOT work, is unpersuasive because 1) the "embodiments" were simply illustrative of the unreliability of the invention as it regards the breadth of the claims and as such, evidence supporting their lack of function is not required, and 2) such an argument does not address the issues raised in the rejection with regard to the nature of the invention, the breadth of the claims, the guidance provided by the specification and the prior art, etc.

Finally, while Examiner agrees with Applicant in that Applicant need not teach every embodiment encompassed by the claims, Applicant's claims are directed to *any* regulatory sequence, which can in any way be affected by *any* bacterial essential protein using *any* reporter gene and *any* bacterial cell. Applicant is required to teach one of ordinary skill in the art how to make and use the invention commensurate in scope with the claims, and the disclosure in combination with the teachings of the prior art are not sufficient to teach one of ordinary skill in the art how to practice a method for identifying any regulatory sequence which is affected by a feedback mechanism on alteration of synthesis or activity of any bacterial essential protein or for identifying modulators of such essential proteins using such regulatory sequences. Neither is the combination of the disclosure with the teachings

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of the prior art sufficient to teach one of ordinary skill in the art how to practice a method for identifying any regulatory sequence whose activity is affected by any feedback mechanism or an alteration of the synthesis or activity of any essential bacterial protein.

Claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record.**

Response to Arguments

Applicant argues that the application as originally filed does provide structural information concerning the test substances and the bacterial essential proteins that can be used in the method of claim 23. Applicant further argues that Example 1 discloses one exemplary way in which a modulator of a bacterial essential protein can be identified such that it is "reasonable to predict that other modulators can be identified

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for other bacterial essential proteins in accordance with claim 23" (see page 15 of the Remarks submitted on 7/27/2006).

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. While the specification may provide some information with regard to substances and bacterial essential proteins which can be used in the claimed methods, the claims do not provide any structural information with regard to the regulatory sequences responsive to alterations in the synthesis or activity of an essential protein. Nor do the claims provide any information with regard to which bacterial essential proteins can be used with which regulator sequences such that a modulator of the bacterial essential protein is identified. The standard for written description is provision of sufficient distinguishing identifying characteristics of the sequences and the factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation and any combination thereof. The standard is not whether is it "reasonable to predict" from one example whether other examples or embodiments are also encompassed within the claimed genus. Examiner fails to see how, based upon the example provided and the other teachings present in the specification and the prior

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art, one of ordinary skill in the art would know that Applicant was in possession of any regulatory sequence which could be used in combination with any bacterial essential protein to identify any modulator of such an essential protein as encompassed by the recited claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann et al (of record). **This rejection is maintained for reasons of record.**

Response to Arguments

Applicant argues that the invention concerns identifying antibiotics, which is done by identifying feedback mechanisms that involve an essential protein. Applicant further argues that the feedback mechanisms are then used to identify modulators of the essential protein. Applicant also argues that

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the document does not refer to identifying particular regulatory sequences. Applicant further argues that the document does not mention feedback mechanisms. Applicant further argues that the Neumann et al document does not disclose the identification of any new modulators of gyrase function, but instead discusses the evaluation of known gyrase inhibitors. Applicant also argues that the document "certainly does not disclose the identification of new antibiotics" (page 16, first paragraph of the Remarks filed 7/27/2006).

Applicant's arguments have been carefully considered and are found persuasive IN PART. Applicant's claims are not drawn to methods of identifying antibiotics, nor to methods of identifying feedback mechanisms; rather Applicant's claims are drawn to methods of identifying regulatory sequences and methods of identifying modulators of bacterial essential proteins. Therefore, arguments drawn toward such methods are unpersuasive. Applicant's argument that the document does not refer to identifying particular regulatory sequences is not persuasive because Neumann et al teach the construction of reporter constructions which utilize the promoter of the *gyrB* and *gyrA* genes (see page 56, lines 7-12 and 37-40). Applicant's argument that the document does not mention feedback mechanisms per se is not persuasive because Neumann et al teach that previous

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experiments had determined that inhibition of the DNA gyrase complex with coumermycin A₁ leads to increased transcription of both gyrA and gyrB in accord with a homeostatic model (see, e.g., page 54, first paragraph).

However, Applicant's argument that the Neumann et al document does not disclose the identification of any new modulators of gyrase function is found persuasive and the rejection of claims 23-26, 28 and 30 **only** as anticipated by Neumann et al is hereby WITHDRAWN.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

October 12, 2006


NANCY VOGEL
PRIMARY EXAMINER